# Exhibit G

State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al., Civil Action No. 03-11226-PBS

Exhibit to the November 25, 2009 Declaration of Christopher C. Palermo in Support of Mylan's Motion for Partial Summary Judgment



## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	) ) ) MDL No. 1456 ) Master File No. 01-CV-12257-PBS
THIS DOCUMENT RELATES TO:	(Original Central District of California No. 03-CV-2238)
State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al. CASE # 1:03-cv-11226-PBS	Hon. Patti B. Saris )

# DEFENDANTS MYLAN LABORATORIES INC.'S AND MYLAN PHARMACEUTICALS INC.'S OBJECTIONS AND RESPONSES TO PLAINTIFF'S FIRST SET OF INTERROGATORIES

Pursuant to Rule 33 of the Federal Rules of Civil Procedure, defendants Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (hereinafter collectively referred to as "Mylan") hereby serve these Objections and Responses to the First Set of Interrogatories ("Interrogatories") propounded by Plaintiff State of California ("California" or "the State").

#### GENERAL OBJECTIONS AND RESERVATION OF RIGHTS

1. Any response is made without waiving or intending to waive, but to the contrary intending to preserve and preserving: (a) the right to object, on the grounds of competency, relevancy, materiality, privilege, or admissibility as evidence for any purpose, or any other ground, to the use of the information provided in this or any subsequent or other proceeding; and (b) the right to object on any ground to other interrogatories, requests to admit, requests for the production of documents, or other discovery proceedings involving or relating to the subject matter of the Interrogatories.

- 2. The information contained herein in connection with the Interrogatories is for use in this litigation only and shall be used for no other purpose.
- 3. Where Mylan states herein that it will produce documents or that it will provide information, it will produce such documents and provide such information subject to and without waiver of, the General Objections and Reservations of Rights, the Objections to Definitions, the Objections to Instructions, the specific objections set forth herein, its Responses And Objections To Plaintiff's First Set of Requests For Production of Documents and Things, and its Responses and Objections to Plaintiff's First Set of Requests for Admissions, and will produce such documents to the extent they exist and can be reasonably obtained.
- 4. The responses made herein are based on Mylan's investigation to date of those sources within its control where it reasonably believes information may exist. Mylan reserves the right to amend or supplement these responses in accordance with the applicable rules and Court orders.
- 5. Mylan objects to the Interrogatorics to the extent they seek information or documents not within Mylan possession, custody, or control.
- 6. Mylan objects to the Interrogatories to the extent they impose on Mylan an obligation to search for and respond with information contained in electronic mail ("e-mail") or other electronically stored data in any format on the grounds that such Interrogatories are overly broad, unduly burdensome, harassing, and not reasonably limited in scope.
- 7. Mylan objects to the Interrogatories to the extent they require Mylan to create data or process an unreasonably large amount of data, some of which

Mylan cannot compute at all and some of which Mylan cannot compute without expending a significant amount of resources, and which is not reasonably calculated to lead to the discovery of admissible evidence.

- 8. Mylan objects to the Interrogatories to the extent they purport to require Mylan to create or analyze data that California itself has the ability to create or analyze by reviewing the documents and data that Mylan has produced or will produce.
- 9. Mylan objects to the Interrogatories to the extent they seek documents or information from documents, including deposition testimony and witness statements, that are subject to protective orders in other jurisdictions.
- 10. Mylan objects to the Interrogatories to the extent that seek information or documents containing trade secrets, proprietary or commercially sensitive or other confidential information, and shall only produce documents or information containing any such information under the terms of the protective order, entered on December 13, 2002 in the Multi-District Litigation entitled *In Re: Pharmaceutical Industry Average Wholesale Price Litigation*, MDL 1456 (D. Mass.) ("Protective Order").
- 11. Mylan objects to the Interrogatories to the extent that they seek documents or information that are: (a) not within the knowledge, possession, custody, or control of Mylan; (b) publicly available; or (c) more appropriately sought from third-parties to whom requests or may be directed.
- 12. Mylan objects to the Interrogatories to the extent they seek information or documents relating to Mylan's activities which are outside the scope of the allegations in the First Amended Complaint In Intervention For Money Damages and

Civil Penalties For Violations of California False Claims Act ("First Amended Complaint").

- burdensome, and not reasonably calculated to lead to admissible evidence to the extent that they seek information or documents relating to drugs not alleged to be at issue in this litigation. Mylan will provide information and documents relating to the drugs manufactured and sold by Mylan Pharmaceuticals Inc. identified in the First Amended Complaint. ("Subject Drugs").
- 14. Mylan objects to the Interrogatories as overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent they seek information or documents concerning any discontinued product after the date of its discontinuation.
- 15. Mylan objects to the Interrogatories to the extent they purport to impose on Mylan obligations that exceed those imposed by the Federal Rules of Civil Procedure and any applicable local rules.
- 16. Mylan objects to the Interrogatories to the extent they seek information or documents protected by the attorney-client privilege, the medical records privilege, the work-product doctrine, the consulting expert privilege, third-party confidentiality agreements or protective orders, or any other applicable privilege, rule, or doctrine.
- 17. Mylan objects to the Interrogatories to the extent they are unduly burdensome, overbroad, oppressive, or seek information or documents neither relevant to this action nor reasonably calculated to lead to the discovery of admissible evidence.

- 18. Mylan objects to the Interrogatories to the extent they are duplicative or redundant.
- 19. Mylan objects to the Interrogatories to the extent they are vague, ambiguous, overbroad, unduly burdensome, or do not identify with sufficient particularity the information sought.
- 20. Mylan objects to the Interrogatories to the extent they seek information from outside the applicable statute of limitations period or after the date of the commencement of this action against Mylan. Mylan will produce documents and information from within the applicable statute of limitations period and prior to the commencement of this action against Mylan ("Subject Time Period").
- 21. Mylan objects to the Interrogatories to the extent they seek information or documents relating to Medicare and other health insurance programs not relevant to this lawsuit, on the grounds that such information or documents are neither relevant to the issues in this action nor reasonably calculated to lead to the discovery of admissible evidence.
- 22. Mylan objects to any implications and to any explicit or implicit characterization of the facts, events, circumstances, or issues in the Interrogatories. Any response by Mylan is not intended to indicate that Mylan agrees with any implication or any explicit or implicit characterization of the facts, events, circumstances, or issues in the Interrogatories, or that such implication or characterization is relevant to this action.
- 23. Mylan objects to the disclosure, under any circumstance, of trade secret information where the probative value of such information in this litigation is greatly exceeded by the potential harm to Mylan if the information were to fall into the

hands of its competitors (including certain co-defendants), and further asserts each and every applicable privilege and rule governing confidentiality to the fullest extent provided by the law.

- 24. Mylan objects to the extent that any of the Interrogatories seek information or documents not related to sales to customers in the State of California and the California Medicaid program on the grounds that such Interrogatories are overly broad, unduly burdensome, and do not seek the discovery of admissible evidence.
- 25. Mylan objects to the Interrogatories to the extent that they seek confidential information or confidential documents relating to a patient.
- 26. Mylan objects to the Interrogatories to the extent they purport to require Mylan to provide information concerning thoughts, knowledge, understanding, or perceptions of unspecified present and former employees, many of whom are no longer employed by Mylan.
- 27. Mylan hereby incorporates by reference as if fully set forth herein any objection or reservation of rights made by any co-defendant in this action to the extent such objection or reservation of rights is not inconsistent with Mylan's position in this litigation.
- 28. Mylan reserves the right to assert additional objections to these Interrogatories as appropriate and to amend or supplement these objections and responses in accordance with the applicable rules and court orders and based on the results of its continuing investigation.

#### **OBJECTIONS TO INSTRUCTIONS**

The General Objections and Reservations of Rights stated above apply to and are incorporated into each and every objection to the instructions set forth below, whether or not expressly incorporated by reference in any individual objection.

- 1. Mylan objects to the Instructions to the extent they seek to impose obligations on Mylan that are greater than, or inconsistent with, Mylan's obligations under the Federal Rules of Civil Procedure and any applicable local rules.
- Mylan objects to the Instructions as overbroad to the extent they purport to require Mylan to provide documents or information not within Mylan's possession, custody or control.
- and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties in this action, including but not limited to "agents," "investigators," "consultants," "Your representative(s)," "Your behalf," and "employees." Mylan further objects to this instruction as overbroad to the extent it purports to require Mylan to provide documents or information in the possession of persons and entities that have no authorization to act on behalf of Mylan and over whom Mylan has no control, including but not limited to former employees. Mylan objects to providing any information or documents within the knowledge, possession, custody or control of Mylan's "attorneys" to the extent such information or documents are protected by the attorney-client privilege, the medical records privilege, the work-product doctrine, the consulting expert privilege, third-party confidentiality agreements or protective orders, or any other applicable privilege, rule, or doctrine.

4. Mylan objects to Instruction No. 8 as overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it requires Mylan to produce documents or information from outside the Subject Time Period. Mylan will produce documents and information from within the Subject Time Period.

## **OBJECTIONS TO DEFINITIONS**

The General Objections and Reservations of Rights and Objections to

Instructions stated above apply to and are incorporated into each and every objection to
the definitions set forth below, whether or not expressly incorporated by reference in any
individual objection.

1. Mylan objects to California's definition of "Document" on the grounds that it is vague, ambiguous, and overbroad. Mylan further objects to this definition to the extent it includes documents that are protected by the attorney-client privilege, the work product doctrine, or any other applicable doctrine or privilege. Mylan further objects to this definition to the extent it seeks to impose obligations on Mylan that are greater than, or inconsistent with, Mylan's obligations under the Federal Rules of Civil Procedure or any applicable local rules. Mylan further objects to this definition to the extent it purports to include within its scope documents or information containing or consisting of proprietary information, trade secrets, or information of a competitively sensitive nature. Mylan further objects to this definition to the extent it purports to include within its scope email or other electronically stored data on the grounds that such a definition is overly broad, unduly burdensome, harassing, and not reasonably limited in scope.

- 2. Mylan objects to California's definitions of "you," "your," "MYLAN," "Defendant," and "affiliated" on the grounds that they are vague and ambiguous and to the extent they purport to include affiliates of Mylan that are not parties to this action. Mylan further objects to these definitions as overbroad to the extent they purport to include persons and entities that have no authorization to act on behalf of Mylan or over whom Mylan has no control. Mylan objects to these definitions as overbroad and unduly burdensome to the extent they purport to require Mylan to produce information or documents from any entity other than Mylan Laboratories Inc. or Mylan Pharmaceuticals Inc.
- 3. Mylan objects to California's definition of "accuracy," "accurate," and "accurately," on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties in this action, including but not limited to "prices," "marketplace," "purchasers," "wholesalers," "pharmacies," "oncology supply houses," and "group purchasing organizations."
- 4. Mylan objects to California's definition of "price representations" on the grounds that it is vague, ambiguous and overbroad. Mylan further objects to this definition to the extent that it is not limited to a reasonable period of time and is not limited to the State of California. Mylan further objects to this definition on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties in this action, including but not limited to "Average Wholesale Price," "Wholesale Acquisition Cost," "Wholesale Net Price," "Direct Price," "List Price," and "Suggested Net Trade."

- 5. Mylan objects to California's definition of "Pharmaceutical" as overly broad and unduly burdensome to the extent that it is not limited to the drugs manufactured and sold by Mylan identified in the First Amended Complaint. Mylan objects to providing information or documents concerning Mylan products that are not at issue in this action.
- 6. Mylan objects to California's definition of "Spread" and "the Spread" on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties in this action, including but not limited to "net cost" and "reimbursement amount."
- 7. Mylan objects to California's definition of "AWP" on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties in this action, including but not limited to "report," "advertise," "market," "publish," "cause to be published," and "average wholesale price."
- 8. Mylan objects to California's definition of "WAC" on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties in this action, including but not limited to "report," "advertise," "market," "publish," "cause to be published," "wholesale acquisition cost," and "wholesaler acquisition cost."
- 9. Mylan objects to California's definition of "Direct Price" on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties in this

action, including but not limited to "report," "advertise," "publish," "cause to be published," "DP," and "direct price."

- 10. Mylan objects to California's definition of "List Price" on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties in this action, including but not limited to "report," "advertise," "publish," "cause to be published," and "list or catalogue price."
- 11. Mylan objects to California's definition of "Best Price" on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties in this action, including but not limited to "report," "disseminate," "best price," "price," and "Medicaid Rebate Program."
- 12. Mylan objects to California's definition of "AMP" on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties in this action, including but not limited to "report," "disseminate," "average manufacturer's price," "price," and "Medicaid Rebate Program."
- 13. Mylan objects to California's definition of "Price Reporting Service" on the grounds that it is vague, ambiguous, and overbroad.
- 14. Mylan objects to California's definition of "disclose," "disclosed," and "disclosure," on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, and undefined, including but not limited to "reveal," "make known," "make public," and "expose."

- 15. Mylan objects to California's definition of "marketed the Spread" on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties in this action, including but not limited to "use of Spreads", "potential profit margins" and "encouraging."
- 16. Mylan objects to California's definition of "facts on which you rely" because the phrase "all related documents" is vague and ambiguous and purports to impose an unduly burdensome requirement.
- 17. Mylan objects to California's definition of "Identified drugs" to the extent that it requires Mylan to produce documents regarding other defendants' drugs.
- 18. Mylan reserves the right to assert additional objections to these Interrogatories as appropriate and to amend or supplement these objections and responses in accordance with the applicable rules and court orders and based on the results of its continuing investigation.

## SPECIFIC RESPONSES AND OBJECTIONS TO INTERROGATORIES

The General Objections and Reservations of Rights, Objections To

Definitions, and Objections to Instructions stated above apply to, and are incorporated in,
the individual responses herein, whether or not expressly incorporated by reference in
such individual responses. Mylan also responds and objects specifically to the individual
Interrogatories as follows:

## INTERROGATORY NO. 1

For each Identified Drug, list each occasion that You reported, or otherwise communicated, prices to Price Reporting Services, including in your answer the date and price(s) reported.

## **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the State of California, the California Medicaid program, and the Subject Time Period. Mylan further objects to this Interrogatory as overbroad and unduly burdensome to the extent that it seeks a list of "each occasion." Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties, including but not limited to "reported" and "otherwise communicated." Mylan further objects this Interrogatory to the extent it purports to require Mylan to summarize information that California itself has the ability to summarize by reviewing documents that Mylan will produce.

Subject to and without waiving the foregoing general and specific objections, Mylan states that it will produce price notification letters in its possession, custody or control, if any, that Mylan Pharmaceuticals Inc. sent to pharmaceutical pricing publications relating to the Subject Drugs during the Subject Time Period.

#### **INTERROGATORY NO. 2**

For each Identified Drug, list each occasion that the prices published by Price Reporting Services reflected the average, estimated or actual price at which such drug was purchased by Medicaid providers.

# MYLAN'S OBJECTIONS AND RESPONSE

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the State of California, the California Medicaid program,

and the Subject Time Period. Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties, including but not limited to "average, estimated or actual price." Mylan further objects this Interrogatory to the extent it seeks information that is not within Mylan's possession, custody and control because it seeks information regarding prices published by third-parties and prices potentially charged to Medicaid providers by third-parties. Mylan further objects to this Interrogatory to the extent that it seeks information more appropriately sought from third-parties to whom requests may be directed.

## **INTERROGATORY NO. 3**

Identify each occasion that You Disclosed to California's Medicaid agency, Medi-Cal, the actual Spreads on the Identified Drugs, or otherwise Disclosed the difference between the AWP and the average, estimated or actual price at which the Identified Drugs were purchased by Medicaid providers.

#### MYLAN'S OBJECTIONS AND RESPONSE

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the Subject Time Period. Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties, including but not limited to "average, estimated or actual price." Mylan further objects this Interrogatory to the extent it incorrectly implies that California needed to be informed by Mylan, or that Mylan had the duty to inform California, that AWP did not

represent acquisition prices paid by providers. California and the federal government knew what AWP was.

Subject to and without waiving any of the foregoing general and specific objections, Mylan states that, subject to the terms of the Protective Order entered in this action, Mylan will produce documents, if any, in Mylan's possession, custody or control which reflect communications between Mylan and California concerning the prices for the Subject Drugs.

Mylan further states that California was in possession of information to compare the AWPs for Mylan's drugs with Mylan's average manufacturer prices ("AMPs"). For Mylan Pharmaceuticals Inc.'s products to be eligible for Medicaid coverage, federal law requires Mylan Pharmaceuticals Inc. to enter into a Rebate Agreement with the Secretary of the Department of Health and Human Services, who enters into the agreement on behalf of States with Medicaid programs, including California. See 42 U.S.C. § 1396r-8(a)(1). The Rebate Agreement requires Mylan Pharmaceuticals Inc. to pay rebates to California based on the AMP for its products. See 42 U.S.C. § 1396r-8(b)(1)(A). The Rebate Agreement requires Mylan Pharmaceuticals Inc. to provide to Centers for Medicare and Medicaid Services ("CMS") on a quarterly basis the AMP for its products that are reimbursed by Medicaid. See 42 U.S.C. § 1396r-8(b)(3). Both federal statute and the Rebate Agreement define AMP as the average unit price paid to Mylan Pharmaceuticals Inc. by wholesalers for its products. See 42 U.S.C. § 1396r-8(k)(1). Under the Rebate Agreement, Mylan Pharmaceuticals Inc. must include in its AMP calculation certain discounts and other price reductions which reduce the price paid for Mylan Pharmaceuticals Inc.'s products. The AMP information was

available to California and California Medicaid officials have the necessary information to determine the AMP for each of Mylan Pharmaceuticals Inc.'s generic products by performing a simple arithmetic calculation, *i.e.*, dividing the Unit Rebate Amount by 11%, the applicable rebate percentage for generic drugs. *See* 42 U.S.C. § 1396r-8(c)(3)(A-B). (Prior to January 1, 1994, the rebate percentage was 10%. *See* 42 U.S.C. § 1396r-8(c)(3)(A-B)).

Mylan further states that, during the Subject Time Period, California and the federal government have been aware that AWP does not reflect providers' acquisition costs. California has received directives and/or reports from the federal government that AWP does not reflect the cost to providers for Mylan's drugs. For example, the Department of Health and Human Services Office of Inspector General Report entitled "Review of Pharmacy Acquisition Costs for Drugs Reimbursed under the Medicaid Prescription Drug Program of the California Department of Health Services," (A-06-95-00062), dated May 1996, stated that in California, AWP exceeded invoice prices by approximately 41.4 percent for generic drugs. Mylan refers California to a letter from John Rodriguez, Deputy Director of the California Department of Health Services, dated March 25, 1996, acknowledging the receipt of the draft OIG report (letter attached to said report at Appendix 4). Indeed, any suggestion by California that AWP should represent what providers pay for drugs is contradicted by California's own Medicaid reimbursement methodology. If AWPs were the same as providers' acquisition costs, a provider could not accept payment at below AWP without losing money on every transaction.

In addition, many other government reports and studies confirm that participating Medicaid states, including California, knew AWPs were only benchmark prices that did not reflect the Providers' actual acquisition costs. For example, in 1984, the HHS-OIG issued a report alerting every state Medicaid agency that "[w]ithin the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price." That AWP is just a benchmark price has been recognized in numerous other public reports, including the following:

In 1977, HCFA told the States that "[i]n order to set estimated acquisition costs which come close to AAC [actual acquisition costs], some states, for example, begin with AWP prices but apply a percentage markdown to determine acquisition costs." HCFA Action Transmittal No. HCFA-AT-77-113 (MMB), Dec. 13, 1977, Medicaid Formula for Determining EAC for Drugs, reprinted in Medicare and Medicaid Guide (CCH) 28,714.

In 1984, the HHS-OIG reported that "AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order discounts, . . . rebates, or free goods that do not appear on the pharmacist's invoices," and recommended that state agencies be precluded from using an undiscounted AWP. The report found pharmacy drug purchases were made at prices averaging approximately 15.93% below AWP, with some at 42% below AWP. Medicaid Action Transmittal No. 84-12 at 3, 6.

In 1989, the HHS-OIG reported: "[w]e continue to believe that AWP is not a reliable price to be used as a basis for making reimbursements for either the Medicaid or Medicare Programs. When AWP is used, we believe it should be discounted." OIG Rep. Concerning Medicaid and Medicare Reimbursement for Drugs at 7.

In 1996 and 1997, the HHS-OIG publicly issued thirteen audit reports finding that AWPs significantly exceed pharmacies' actual acquisition costs.

In May 2000, the California Medicaid program received average wholesale market pricing information for about 400 national drug codes compiled by the U.S. Department of Justice ("DOJ"), without reliance on published AWPs. All of the states that participated in the Medicaid program, including California, were told actual acquisition costs may be even lower than the DOJ wholesale prices, "because purchasers often receive further discounts, below the advertised wholesale catalog price . . . ."

## **INTERROGATORY NO. 4**

Identify each occasion that You sought clarification or guidance from California's Medicaid agency, Medi-Cal, regarding the meaning, intent or goal of any provision or term of any regulation, statute, or policy regarding the setting of reimbursement for the Identified Drugs.

## MYLAN'S OBJECTIONS AND RESPONSE

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the Subject Time Period and the scope of the First Amended Complaint. Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties, including but not limited to "clarification," "guidance," "regarding," "meaning," "intent," and "goal." Mylan further objects to this Interrogatory to the extent it seeks information to which California has equal or greater access.

Subject to and without waiving any of the foregoing general and specific objections, Mylan states that, subject to the terms of the Protective Order entered in this action, Mylan will produce documents, if any, in Mylan's possession, custody or control

which reflect communications between Mylan and California potentially responsive to this Interrogatory.

#### **INTERROGATORY NO. 5**

Identify each occasion that You sought clarification or guidance from California's Medicaid agency, Medi-Cal, regarding the meaning of AWP, WAC, Direct Price, List Price, or estimated acquisition cost.

## **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the Subject Time Period and the scope of the First Amended Complaint. Mylan further objects to this Interrogatory as vague and ambiguous because, inter alia, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties, including but not limited to "clarification," "guidance," "regarding," and "estimated acquisition cost." Mylan further objects this Interrogatory to the extent it seeks information to which California has equal or greater access.

Subject to and without waiving any of the foregoing general and specific objections, Mylan states that, subject to the terms of the Protective Order entered in this action, Mylan will produce documents, if any, in Mylan's possession, custody or control which reflect communications between Mylan and California potentially responsive to this Interrogatory.

#### **INTERROGATORY NO. 6**

Identify all of Your employees who were involved in the sales and marketing of the Identified Drugs. Include in your answer their position, the dates of their employment and last known address and phone number.

## **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the State of California, the California Medicaid program, the Subject Time Period, and the scope of the First Amended Complaint.

Subject to and without waiving any of the foregoing general and specific objections, Mylan states that Mylan Laboratories Inc. is a holding company and does not manufacture, market or sell drugs. Mylan further states that the following current and former employees are knowledgeable concerning the sales and marketing of Mylan Pharmaceuticals Inc.'s Subject Drugs: Robert Potter, Dan King, Jack Walsh, Drew Blowers, Robert Cunard, Dale Martin, Bob Lombardi, Jason Harper, Brett Baker, Roderick Jackson, Brad Cunningham, Stephen Hitemeyer, Mark Jordan, Romney Spencer, Ernie Frederickson, Laurie Schwartz, Steve Pickens, Tom Cogan, and Bernie Hawkins. Mylan further states that these individuals should be contacted through Mylan's counsel, Kelley Drye & Warren LLP, 101 Park Avenue, New York, New York.

## **INTERROGATORY NO. 7**

Identify all firms, organizations and/or individuals hired by You to engage in any lobbying efforts directed at the California legislature (including any legislative Committee, individual state legislator, or the Committee or legislator's staff) with regard to the California Medicaid program's reimbursement for prescription drugs.

## **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the Subject Drugs, the Subject Time Period, and the scope

of the First Amended Complaint. Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, or undefined, including but not limited to "lobbying efforts."

## **INTERROGATORY NO. 8**

Identify all instances or occasions on which You contacted or otherwise communicated with the California legislature (including any legislative Committee, individual state legislator, or the Committee or legislator's staff) in connection with:

- (a) any of Your Pharmaceuticals, and
- (b) any legislation, rule-making or policies related to reimbursement for Your Pharmaceuticals.

## **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the Subject Drugs, the Subject Time Period, and the scope of the First Amended Complaint. Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, or undefined, including but not limited to "rule-making," "policies," and "reimbursement." Mylan further objects this Interrogatory to the extent it seeks information to which California has equal or greater access.

#### **INTERROGATORY NO. 9**

Identify all employees, agents or outside firms involved with the determination and/or reporting of the AWP, WAC, Direct Price, or List Price for the Identified Drugs to Price Reporting Services or California's Medicaid program.

#### MYLAN'S OBJECTIONS AND RESPONSE

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the

extent that it is not limited to the Subject Time Period. Mylan further objects to this Interrogatory as overbroad and unduly burdensome to the extent it seeks the identity of "all employees, agents or outside firms." Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties, including but not limited to "agents," "outside firms," "determination," and "reporting."

Subject to and without waiving any of the foregoing general and specific objections, Mylan states that Robert Cunard, Joe Duda, John Ford, Roderick Jackson, Jodi Eichelberger, Robert Tighe, Robert Potter, David Workman, and Steve Krinke are the Mylan employees most knowledgeable concerning the determination and reporting of prices for the Subject Drugs. Mylan further states that these individuals should be contacted through Mylan's counsel, Kelley Drye & Warren LLP, 101 Park Avenue, New York, New York.

#### **INTERROGATORY NO. 10**

Did any of Your employees or representatives ever use the Spread or potential profit margins on the Identified Drugs when selling or marketing those drugs, and, if so:

- (a) identify each such person, and
- (b) all documents reflecting, referring or relating to such practices.

## **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the State of California, the California Medicaid program, and the Subject Time Period. Mylan objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous,

undefined, or interpreted differently by the parties, including but not limited to "use the Spread," "potential profit margins," "reflecting," "referring," and "relating."

Subject to and without waiving the foregoing general and specific objections, Mylan states that the term "spread" is not typically used by its personnel. Mylan further states that, while Mylan personnel occasionally conduct internal analyses of relative pricing, and occasionally respond to inquiries from customers regarding such pricing, it is Mylan's policy not to make affirmative use of the "spread" in its distribution, marketing, sales or promotion activities.

#### **INTERROGATORY NO. 11**

Did You ever instruct any employee or representative to use the Spread or potential profit margins on the Identified Drugs when selling or marketing those Pharmaceuticals, and, if so, identify:

- (a) all employees or representatives who gave such instruction,
- (b) all employees and representatives who were so instructed,
- (c) the time and content of such instruction, and
- (d) identify all documents reflecting, relating to or referring to such instruction.

## **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the State of California, the California Medicaid program, and the Subject Time Period. Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties, including but not limited to "use the Spread," "potential profit margins," "reflecting," "referring," and "relating."

Subject to and without waiving the foregoing general and specific objections, Mylan refers California to its response to Interrogatory No. 10.

## **INTERROGATORY NO. 12**

Set forth the definition of AWP, as that term has been used by You when used in the course of business during the period January 1, 1994 through December 31, 2004, and identify any regulation or authority that supports that definition. If the definition has changed over time, identify it by year.

## **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, or undefined, including but not limited to "course of business" and "authority." Mylan further objects to this Interrogatory to the extent that it incorrectly assumes that Mylan had created its own definition of AWP.

Subject to and without waiving the foregoing general and specific objections, Mylan states that AWP for a Mylan Pharmaceuticals Inc. product is reported by Mylan Pharmaceuticals Inc. with reference to AWP for a brand company's therapeutically-equivalent product, as reported by American Druggist, First Data Bank or another nationally recognized publication. AWP reported by Mylan Pharmaceuticals Inc., however, is not necessarily the same as the AWP that might be independently established and reported by the publisher. Mylan further states that AWP is used to identify the availability of a product, to determine whether the product is categorized as a brand or generic, and as a reference point for certain reimbursement methodologies. When Mylan Pharmaceuticals Inc. launches a drug, it sets its AWP below the prevailing brand drug price at a level that will ensure that Mylan Pharmaceuticals Inc.'s drugs are classified as generic and will be competitive. This practice is consistent with industry practice. Mylan further states that AWP does not take into account any discounts, chargebacks, rebates, or other reductions in price that may be provided. Mylan further

states that this has been the generally recognized definition of AWP throughout the pharmaceutical industry during the Subject Time Period.

Mylan further states that, during the Subject Time Period, California and the federal government have been aware that AWP does not reflect providers' acquisition costs. California has received directives and/or reports from the federal government that AWP does not reflect the cost to providers for Mylan's drugs. For example, the Department of Health and Human Services Office of Inspector General Report entitled "Review of Pharmacy Acquisition Costs for Drugs Reimbursed under the Medicaid Prescription Drug Program of the California Department of Health Services," (A-06-95-00062), dated May 1996, stated that in California, AWP exceeded invoice prices by approximately 41.4 percent for generic drugs. Mylan refers California to a letter from John Rodriguez, Deputy Director of the California Department of Health Services, dated March 25, 1996, acknowledging the receipt of the draft OIG report (letter attached to said report at Appendix 4). Indeed, any suggestion by California that AWP should represent what providers pay for drugs is contradicted by California's own Medicaid reimbursement methodology. If AWPs were the same as providers' acquisition costs, a provider could not accept payment at below AWP without losing money on every transaction.

#### **INTERROGATORY NO. 13**

With respect to each definition set forth in your answer to Interrogatory 12, identify all instances in which Your definition was communicated to the public, or any governmental entity.

## **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the State of California, the California Medicaid program, the Subject Time Period, and the scope of the First Amended Complaint. Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, or undefined, including but not limited to "communicated" "the public," and "governmental entity." Mylan further objects to this Interrogatory to the extent that incorrectly assumes that Mylan had created its own definition of AWP.

Subject to and without waiving any of the foregoing general and specific objections, Mylan states that California, the federal government, and other State Medicaid agencies have known exactly what AWP is and refers to and incorporates herein its response to Interrogatory No. 3.

#### **INTERROGATORY NO. 14**

Identify all employees, or former employees, who were the source of the above definition(s) or who have knowledge as to the meaning of AWP as used by You.

#### MYLAN'S OBJECTIONS AND RESPONSE

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the Subject Time Period. Mylan further objects to this Interrogatory as overbroad and unduly burdensome to the extent that it seeks the identity

of "all employees, or former employees." Mylan further objects to this Interrogatory to the extent that incorrectly assumes that Mylan had created its own definition of AWP.

Subject to and without waiving the foregoing general and specific objections, Mylan states that its understanding of the term "AWP" was not developed or derived internally but is rather consistent with the meaning of the term as it is used throughout the pharmaceutical industry. Mylan further states that Brian Roman, David Workman, and Steve Krinke have knowledge of the meaning of the term "AWP" as that term is used by Mylan.

#### **INTERROGATORY NO. 15**

During the Relevant Time Period, did any person at Your company question, inquire or otherwise express a concern whether the existence of a spread between AWP and the prices at which Pharmaceuticals were purchased by Medicaid providers violated the law, was misleading, or may result in excessive reimbursement?

# **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the State of California, the California Medicaid program, the Subject Drugs, the Subject Time Period, and the scope of the First Amended Complaint. Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties, including but not limited to "spread" "AWP," and "prices." Mylan further objects to this Interrogatory to the extent that it incorrectly implies that Mylan engaged in unlawful or misleading conduct. Mylan further objects to this Interrogatory to the extent that it incorrectly implies that Mylan created or

maintained a "spread" on its drugs or that California paid "excessive reimbursement" for Mylan's drugs.

Subject to and without waiving any of the foregoing general and specific objections, Mylan states that California has known that AWP does not represent providers' actual acquisition costs for drugs and refers to and incorporates herein its response to Interrogatory No. 3. Mylan has not represented to the federal government or California that the AWP published for its products represented providers' actual acquisition costs or prices paid by anyone.

Mylan further states that the existence of a "spread" between AWP and the prices at which Mylan's drugs were purchased by Medicaid providers did not violate the law, was not misleading, and did not cause California to make excessive reimbursement payments. California actively decided to use a reimbursement methodology with a built-in "spread" between a provider's actual acquisition costs and reimbursement amounts to serve its own needs. California is required by law to ensure that all Medicaid beneficiaries in every corner of the State have access to prescription drugs. 42 U.S.C. § 1396a(a)(30)(A) provides: "A state plan for medical assistance must... assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area...." Since Providers are not required by law to participate in the Medicaid program, California needs to ensure that enough Providers voluntarily participate. In order to ensure participation, California must give Providers a financial incentive to stay in the program. California knew that its reimbursement methodology

for the ingredient portion did not approximate Providers' costs to acquire the drugs, but did not change its reimbursement methodology because, among other reasons, it had to ensure that a sufficient number of Providers enrolled to ensure access to care for Medicaid beneficiaries.

The federal government and California have never limited Medicaid reimbursement payments to a provider's acquisition cost for a product by its use of AWP. Consistent with federal regulations and subject to approval by CMS, California has the right to establish its reimbursement methodology for prescription drugs. 42 C.F.R. §447.331. It could have established a reimbursement system based on an undiscounted AWP, as some states have done, or it could have established one based upon providers' actual acquisition costs, as other states have done. California's use of a discounted AWP in its reimbursement methodology was the result of political negotiations between the California Medicaid agency and Medicaid providers and represents California's effort to balance the political goals of the Medicaid program. California Medicaid has used AWP as a benchmark price to ensure providers cover their costs and receive a profit and beneficiaries have access to medical care. Reimbursement for prescription drugs is intended to cover the ingredient cost of the drug, the costs incurred by a provider in dispensing the product, and a reasonable profit to the provider. California's dispensing fees do not cover dispensing costs incurred by providers, much less provide a profit. As a result, California has used, and continues to use, an AWP-based reimbursement methodology to compensate for this shortfall in dispensing fees and to ensure that providers earn a profit on Medicaid transactions.

California was free at all times to change its pharmaceutical reimbursement under its Medicaid program to a non-AWP-based methodology. In addition to the published AWPs for Mylan's products, California had access to a number of other prices for Mylan's products, including published WAC prices, Federal Supply Schedule prices, Department of Veterans Affairs prices, and AMPs. California could have compared the published AWPs for Mylan's products with any one of these prices and used one of the lower prices in its reimbursement methodology.

Through its AWP-based reimbursement methodology, California's Medicaid program knowingly provides larger "spreads" for generic drugs than for brandname drugs in order to provide an incentive for pharmacies to dispense lower-cost generic drugs. Generic drugs are typically less costly than brand-name drugs. Therefore, even though California's reimbursement for a generic drug may give a provider a larger "spread" than reimbursement for a brand name drug, the total reimbursement payment for the generic drug will still be lower than that for a brand-name drug, thereby saving California money. As "spreads" for generic drugs increase, California benefits, because the larger spreads increase incentives for providers to dispense generic drugs. Moreover, contrary to California's claims, Mylan does not benefit from increased spreads.

The Medicaid program is jointly funded by California and federal governments, and the federal government has funded at least 50% of all expenditures of the California Medicaid program. In order to obtain federal funds, California was required to submit its prescription drug reimbursement methodology to CMS for approval. CMS approved California's reimbursement methodology with knowledge: (1) of Mylan's AMPs as compared to Mylan's AWPs; (2) that the reimbursement

methodology included a spread between actual acquisition cost and reimbursement amount; and (3) that Medicaid programs in other states were reimbursing at lower amounts, namely those that reimbursed at actual acquisition cost. In other words, CMS effectively approved of and ratified the spread California incorporated into its reimbursement methodology.

Additionally, as California's own claims data will confirm, prices charged in market transactions by providers, wholesalers, and others exceed the AWPs of generic products, including Mylan's products.

## **INTERROGATORY NO. 16**

With respect to your answer to the previous interrogatory, identify all persons with knowledge of such inquiry.

#### **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan refers and incorporates herein its objections and response to Interrogatory No. 15.

## **INTERROGATORY NO. 17**

For each Identified Drug, list each occasion that You reported, or otherwise communicated, to Price Reporting Services a change in the reported AWP, including in your answer the date, the NDC and the reported change.

## MYLAN'S OBJECTIONS AND RESPONSE

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the State of California, the California Medicaid program, and the Subject Time Period. Mylan further objects to this Interrogatory as overbroad and unduly burdensome to the extent that it seeks a list of "each occasion." Mylan

further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties, including but not limited to "reported," "otherwise communicated," and "reported AWP." Mylan further objects this Interrogatory to the extent it purports to require Mylan to summarize information that California itself has the ability to summarize by reviewing documents that Mylan will produce.

Subject to and without waiving the foregoing general and specific objections, Mylan states that, subject to the terms of the Protective Order entered in this action, it will produce price notification letters in its possession, custody or control, if any, that Mylan Pharmaceuticals Inc. sent to pharmaceutical pricing publications relating to the Subject Drugs during the Subject Time Period which California can use to determine the AWPs Mylan reported to "Price Reporting Services", including any changes to the AWPs reported.

#### **INTERROGATORY NO. 18**

With respect to your answer to the previous interrogatory, identify the reason(s) for each such change in the reported AWP.

#### **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the State of California, the California Medicaid program, and the Subject Time Period. Mylan further objects to this Interrogatory as overbroad and unduly burdensome to the extent that it seeks reasons "for each such change." Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it

contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties, including but not limited to "reported AWP."

Subject to and without waiving any of the foregoing general and specific objections, Mylan states that Mylan Pharmaceuticals Inc. is a manufacturer of generic drugs and is in a competitive business. As part of this competitive business, Mylan Pharmaceuticals Inc. periodically adjusts its prices due to changes in market and competitive conditions relating to, for example, the pricing of the competing brand product, the pricing of other generic competitors in the marketplace, its categorization as a generic or brand in pricing compendia, changes in manufacturing costs, and raw material availability.

#### **INTERROGATORY NO. 19**

Do you contend that, during the Relevant Time Period, the AWPs for each of the Identified Drugs were a fair and accurate reporting of the price at which wholesalers sold Your Pharmaceuticals to their customers, including physicians, pharmacies or others negotiating prices directly with the company, after all rebates, free goods, and discounts have been included in the price?

#### MYLAN'S OBJECTIONS AND RESPONSE

Mylan objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains terms that are themselves vague, ambiguous, undefined, or interpreted differently by the parties, including but not limited to "AWPs," "fair and accurate reporting," "wholesalers," "others negotiating prices directly with the company," "rebates," "free goods," "discounts," and "price." Mylan further objects to this Interrogatory to the extent that it seeks information that is not within Mylan's possession, custody, or control to the extent it seeks information concerning wholesalers' prices.

Subject to and without waiving the foregoing general and specific objections, Mylan states that AWP for a Mylan product is reported by Mylan with reference to AWP for a brand company's therapeutically-equivalent product, as reported by American Druggist, First Data Bank or another nationally recognized publication. AWP reported by Mylan, however, is not necessarily the same as the AWP that might be independently established and reported by the publisher. Mylan further states that AWP is used as to identify the availability of a product, to determine whether the product is categorized as a brand or generic, and as a reference point for certain reimbursement methodologies. When Mylan launches a drug, it sets its AWP below the prevailing brand drug price at a level that will ensure that Mylan's drugs are classified as generic and will be competitive. This practice is consistent with industry practice. Mylan further states that AWP does not take into account any discounts, chargebacks, rebates, or other reductions in price that may be provided. Mylan further states that this has been the generally recognized definition of AWP throughout the pharmaceutical industry during the Subject Time Period.

Mylan further states that California, the federal government, and other State Medicaid agencies have known exactly what AWP is and refers to and incorporates herein its response to Interrogatory No. 3.

## **INTERROGATORY NO. 20**

Please state all facts which support your answer to the previous interrogatory.

#### MYLAN'S OBJECTIONS AND RESPONSE

Mylan refers to and incorporates herein its objections and response to Interrogatory No. 19.

#### **INTERROGATORY NO. 21**

If you assert an affirmative defense based upon "established industry practice," set forth all factual support that Your conduct as alleged in the First Amended Complaint in Intervention was justified or was in accordance with established industry practice.

## MYLAN'S OBJECTIONS AND RESPONSE

Mylan objects to this Interrogatory as overly broad and unduly burdensome to the extent that it seeks "all factual support." Mylan further objects to this Interrogatory as premature since discovery of California is only now beginning, and Mylan cannot be expected to identify all relevant facts and documents at this early stage in the litigation. Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains words that are themselves vague, ambiguous, undefined, and interpreted differently by the parties, including but not limited to "established industry practice" and "AWPs."

Subject to and without waiving the foregoing general and specific objections, Mylan refers to and incorporates herein its response to Interrogatory Nos. 3, 12 and 15. Mylan further states:

- a. Mylan has not engaged in conduct that was improper, fraudulent, or unlawful as alleged in Plaintiff's Amended Complaint.
- b. Claims for reimbursement under the California Medicaid program are filed by providers, not Mylan, and Mylan has never caused any provider to file a false claim. California pays Medicaid reimbursements directly to Medicaid providers, not to Mylan. Mylan has not received any money from any Medicaid reimbursement payment made by California.

- c. Mylan has never reported "false" or "inflated" Average Wholesale Prices or AWPs. California and the federal government have never provided any guidance or instructions to Mylan on any specific calculation of AWP. Thus, there can be no basis for characterizing an AWP set by Mylan Pharmaceuticals Inc. as "false" and no basis for the alleged injuries California allegedly suffered due to Mylan's alleged reporting of AWPs.
- d. While Mylan Pharmaceuticals Inc. reports AWPs to First

  DataBank and other pricing compendia, First DataBank has publicly stated that it

  published its own AWP prices after making its own determination concerning the

  reported values.
- e. Mylan further states that reimbursement payments made by California's Medicaid program were often not based on published AWPs for Mylan's drugs. California has reimbursed at the lowest of four possible numbers: (1) the drug's Direct Price or AWP less a certain percentage; (2) a drug's Federal Allowable Cost ("FAC"), a maximum reimbursement rate for a drug set by the federal government; (3) Maximum Allowable Ingredient Cost ("MAIC"), a maximum reimbursement rate for a drug set by California; or (4) the Medicaid provider's usual and customary charge to the general public. 42 C.F.R. § 447.331; Cal. Code Reg. Title 22, § 51513. Therefore, when the California Medicaid program pays reimbursements for Mylan's drugs based on AWP, it is paying the lowest of four possible prices, including the usual and customary charge, *i.e.*, market price, charged to the general public.

#### **INTERROGATORY NO. 22**

Do you contend that public information existed disclosing that the AWP for the Identified Drugs exceeded actual prices at which the Identified

Drugs were purchased by Medicaid providers? If so, for each of the Identified Drugs, and for the years January 1, 1994 through December 31, 2004:

- (a) Set forth the reported AWP;
- (b) Set forth the actual prices and average price at which the Identified Drugs were purchased by Medicaid providers; and
- (c) Identify where the Spread between AWP and the actual price was disclosed to the public or to any governmental entity.

#### MYLAN'S OBJECTIONS AND RESPONSE

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the State of California, the California Medicaid program, and the Subject Time Period. Mylan further objects to this Interrogatory to the extent it requires Mylan to identify documents that are not within its possession, custody, or control. Mylan further objects to this Interrogatory as unduly burdensome and not reasonably limited in scope to the extent it requires Mylan to conduct a broad search of publicly available documents spanning "several decades" to which Plaintiff has equal access. Mylan further objects to this Interrogatory to the extent it requires the production of documents discovered through a search protected by the work product doctrine. Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains words that are themselves vague, ambiguous, undefined, and interpreted differently by the parties, including but not limited to "AWP," "actual prices," "average price," "disclosed," "the public," and "governmental entity."

Subject to and without waiving the foregoing general and specific objections, Mylan refers to and incorporates herein its response to Interrogatory No. 3, 15 and 21.

Mylan further states that discovery in various litigation is now unearthing a substantial body of documents available to federal and state Medicaid agencies for many years showing that AWP does not reflect actual acquisition costs. Mylan refers California to the following documents:

# Representative Federal materials, including but not limited to documents from the Department of Health and Human Services' Office of Inspector General:

DESCRIPTION	DATE
Federal Register, Wednesday, November 27, 1974, Volume 39, Number 230,	11/74
Part II, containing HCFA, 45 CFR Part 250, Proposed Reimbursement of	
Drug Cost-Medical Assistance Program	
Title IX, Social Security Act: Limitation on Payment or Reimbursement for	12/77
Drugs: Estimated Acquisition Cost (EAC); ¶128, 714	
Changes to the Medicaid Prescription Drug Program Could Save Millions	09/84
Medicare and Medicaid Guide ¶ 34,157 Medicaid-Limitation on Payment for	1984
Drugs	
Majority Staff Report of the Special Committee on Aging US Senate:	1989
Prescription Drug Prices: Are We Getting Our Money's Worth?	
Office of the Inspector General ("OIG") Report Concerning Medicaid and	10/89
Medicare Reimbursement for Drugs, ¶ 38,215	
Comparison of Reimbursement Prices for Multiple-Source Prescription	03/91
Drugs in the United States and Canada	
Cost of Dialysis-Related Drugs	10/92
Physicians' Costs for Chemotherapy Drugs	11/92
Memorandum to All Associate Regional Administrators Division of	08/94
Medicaid from Sally Richardson, Director of Medicaid Bureau, regarding	
Expiration of Pharmacy Reimbursement Moratorium-Information	
Statement by Congressman Pete Stark in the House of Representatives (with	02/96
proposed bill)	
Medicare Payment for Nebulizer Drugs	02/96
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the	05/96
Medicaid Prescription Drug Program of the California Department of Health	
Services	
Appropriateness of Medicare Prescription drug Allowances	05/96
Payment for Enteral Nutrition: Medicare and Other Payers	05/96
Suppliers' Acquisition Costs for Albuterol Sulfate	06/96
A Comparison of Albuterol Sulfate Prices	06/96
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the	07/96
Medicaid Prescription Drug Program of the Montana Department of Public	
Health and Human Services	
Review of Pharmacy Acquisition Costs for Drugs reimbursed Under the	08/96
Medicaid Prescription Drug Program of the Florida Agency for Health Care	men andresse

Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the North Carolina Department of Human Services  Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Delaware Department of Health and Social Services  Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Virginia Department of Medical Assistance Services  Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Nebraska Department of Social Services  Review of Pharmacy Acquisition Cost for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the New Jersey Department of Human Services  Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Missouri Department of Social Services  Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the District of Columbia Department of Human Services  Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Maryland Department of Health and Mental Hygiene  Questionable Practices Involving Nebulizer Drug Therapy  O3/97  Medicare Reimbursement for Parenteral Nutrition  Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug  Products  Excessive Medicare Payments for Prescription Drugs  Excessive Medicare Payments for Prescription Drugs  Weekly Radio Address to the Nation, 1997 WL 767416  12/97  Program Memorandum Change Request # 298  Need to Establish Connection Between the Calculation of Medicaid Drug  Rebates and Reimbursement for Medicaid Drugs  The Impact of High-Priced Generic Drugs on Medicare and Medicaid  O7/98  Are Medicare Allowances for Albuterol Sulfate Reasonable?  Comparing Drug Reimbursement: Medicare and Department of Veterans  Affairs  Medicaid Pharmacy - Acquisition Cost of Brand Name Prescription Drug  P	Administration	
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Report to Honorable Secretary Michael O. Leavitt, Dept. of Health and	
Human Service and The United States Congress	
How Inflated Published Prices Affect Drugs Considered for the Federal	09/05
Upper Limit List	
A Comparison of Average Sales Prices to Widely Available Market Prices:	06/06
Fourth Quarter 2005	
Comparison of Fourth-Quarter 2005 Average Sale Prices to Average	07/06
Manufacturer Prices: Impact on Medicare Reimbursement for Second	
Quarter 2006	
GAO – Medicaid Outpatient Prescription Drugs Estimated 2007 Federal	12/06
Upper Limits for Reimbursement Compared with Retail Pharmacy	
Acquisition Cost	
Congressional Budget Office: Prescription Drug Pricing in the Private Sector	01/07
Testimony of Lewis Morris before the House Oversight and Government	02/07
Reform Committee, "Allegations of Waste, Fraud and Abuse in	
Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and	
the Federal Taxpayer	
Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit	06/07
Program	

# Representative documents from First DataBank and other Third Parties:

DESCRIPTION	DATE
Average Wholesale Price, FDB-AWP 02023	No date
First DataBank Monthly Interest, "Understanding AWP"	09/00/1991
Barron's article entitled "Hooked on Drugs: Why do Insurers Pay Such	06/10/1996
Outrageous Prices for Pharmaceuticals?"	
Price Alert, "Demystifying AWP?"	06/15/1991
First DataBank, Inc. Price Alert sent by Kay Morgan, "Average Wholesale	03/15/2000
Price"	
Website Page from First Data Bank - The Knowledge Insider - Frequently	08/14/2002
Asked Questions	
FDB Website, FDB-AWP 02005-02006	11/04/2002
Price Alert-Guide to AWP Pricing, FDB-AWP 13140 and 131343	12/15/2002

# **INTERROGATORY NO. 23**

If you contend that the State of California has not been damaged, set forth all facts and identify all facts and documents which support such contention.

Mylan objects to this Interrogatory as overbroad and unduly burdensome to the extent it seeks the identity of "all facts and documents." Mylan further objects to this Interrogatory because the term "damaged" is vague and ambiguous. Mylan further objects to this Interrogatory on the grounds that it is premature. Discovery has not yet concluded in this action and Mylan has not yet completed its investigation, analysis, or discovery of the facts relating to this case.

Subject to and without waiving the foregoing general and specific objections, Mylan refers to and incorporates herein its responses to Interrogatory Nos. 3, 15, 21, and 22. Mylan further states as follows:

- a. Federal law requires that California's Medicaid payments "are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." 42 U.S.C. § 1396a(a)(30)(A). Participation by providers in the California Medicaid program is voluntary. To ensure that its Medicaid beneficiaries have adequate access to medical care, the California Medicaid program utilizes an AWP-based reimbursement methodology to provide an economic incentive for providers' participation. In so doing, California balances the interests of three constituencies: the beneficiaries (to whom California was obligated to maintain access), the providers (who needed an economic incentive to serve California Medicaid clients), and the taxpayers (to whom California was accountable for costs.)
- b. The Government has never limited Medicaid reimbursement payments to a provider's acquisition cost for a product by its use of AWP.

Reimbursement for prescription drugs is intended to cover the ingredient cost of the drug, the costs incurred by a provider in dispensing the product, and a reasonable profit to the provider. California's dispensing fees do not cover dispensing costs incurred by the provider, much less provide a profit. As a result, California has used, and continues to use, an AWP-based reimbursement methodology to compensate for this shortfall in dispensing fees and to ensure that providers earn a profit on Medicaid transactions.

California was free at all times to change its pharmaceutical reimbursement under its Medicaid program to a non-AWP-based methodology. Upon information and belief, California has periodically considered, and rejected, alternative pharmaceutical reimbursement methodologies, including methodologies that were not based on AWP.

c. Through its AWP-based reimbursement methodology, California's Medicaid program knowingly provides larger "spreads" or margins for generic drugs than for brand-name drugs in order to provide an incentive for pharmacies to dispense lower-cost generic drugs. Generic drugs are typically less costly than brand-name drugs. Therefore, even though California's reimbursement for a generic drug may give a provider a larger "spread" than a reimbursement for a brand name drug, its total reimbursement payment for the generic drug will still be lower than that for a brand-name drug, thereby saving California money. As "spreads" for generic drugs increase, California benefits, because the larger spreads increase incentives for providers to dispense generic drugs. Moreover, contrary to California's claims, Mylan does not benefit from increased spreads.

d. As California's own claims data will confirm, prices charged in market transactions by providers, wholesalers and others exceed the AWPs of generic products, including Mylan Pharmaceuticals Inc.'s products.

#### **INTERROGATORY NO. 24**

For each sale of an Identified Drug made by Your company to any wholesaler, retailer, pharmacy, provider, or other entity for use by a California resident during the Relevant Time Period, identify the following information:

- (a) date of sale;
- (b) the quantity of the Identified Drug sold;
- (c) to whom the Identified Drug was sold, and
- (d) the price the purchaser paid for the Subject Drug.

#### **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as overbroad and unduly burdensome to the extent that it seeks information concerning "each sale of an Identified Drug made by [Mylan]." Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains words that are themselves vague, ambiguous, undefined, and interpreted differently by the parties, including but not limited to "price", "wholesaler" "retailer," "provider," "disclosed," "the public," and "governmental entity."

Subject to and without waiving the foregoing general and specific objections, Mylan states that this Interrogatory, as presently written, is unnecessarily and oppressively broad and unduly burdensome. Mylan agrees to confer with Plaintiff regarding the information sought in this Interrogatory to address these objections.

#### **INTERROGATORY NO. 25**

Identify all of Your ownership interests in any pharmacy or other business(es) supplying prescription drugs to Medicaid recipients.

Mylan objects to this Request as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence because it is not limited to the State of California, the California Medicaid Program, the Subject Drugs, the Subject Time Period, and the scope of First Amended Complaint. Mylan further objects to this Interrogatory as vague and ambiguous because the term "other business(es)" is vague and ambiguous. Mylan further objects to this Interrogatory to the extent it seeks information regarding shares it holds in publicly traded companies.

Subject to and without waiving the foregoing general and specific objections, Mylan states that it does not have any ownership interest in any pharmacy or business providing prescription drugs directly to Medicaid beneficiaries.

#### **INTERROGATORY NO. 26**

If any of the business records pertaining to Your business are maintained in the ordinary course of business by any entity other than you, please identify the records and the person or entity who maintains them.

#### MYLAN'S OBJECTIONS AND RESPONSE

Mylan objects to this Interrogatory as overbroad and unduly burdensome in that it is not limited to the State of California, the California Medicaid program, the scope of the First Amended Complaint, and the Subject Drugs.

Subject to and without waiving the foregoing general and specific objections, Mylan states that it maintains its own records.

#### **INTERROGATORY NO. 27**

Identify the person or persons most knowledgeable of the system or systems for maintaining the records called for in the State of California's First Request for the Production of Documents propounded on You.

Mylan incorporates herein by reference its objections to the State of California's First Request for the Production of Documents. Mylan further objects to this Interrogatory as vague and ambiguous because the phrase "system or systems of maintaining records" is vague and ambiguous.

Subject to and without waiving the foregoing general and specific objections, Mylan states that there is no single document retention system or person "most knowledgeable" about the document retention systems maintained by Mylan.

# **INTERROGATORY NO. 28**

Describe Your record retention policy or policies in effect during the Relevant Time Period with regard to each of the categories of documents requested in the State of California's First Request for the Production of Documents propounded on You.

# **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan incorporates herein by reference its objections to the State of California's First Request for the Production of Documents. Mylan objects to this Interrogatory as overbroad and unduly burdensome in that it is not limited to the State of California, the California Medicaid program, the Subject Drugs, the Subject Time Period, and the scope of the First Amended Complaint.

Subject to and without waiving the foregoing general and specific objections, Mylan states that, during the Subject Time Period, Mylan's policy has been to retain documents in accordance with applicable laws. In cases involving litigation, documents relevant to the particular litigation are preserved.

#### **INTERROGATORY NO. 29**

Describe Your e-mail system in effect during the Relevant Time Period, and, with regard thereto, (a) identify the person or persons responsible for maintaining archives of e-mails sent or received by any of Your employees; and (b) describe Your email retention policy or policies in effect during the Relevant Time Period.

# **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as overbroad and unduly burdensome in that it is not limited to the State of California, the California Medicaid program, the Subject Drugs, the Subject Time Period, and the scope of the First Amended Complaint. Mylan further objects to this Interrogatory as overbroad and unduly burdensome to the extent the phrase "email retention policy or policies" refers to email retention policies not related to documents potentially responsive in this action.

Subject to and without waiving any the foregoing general and specific objections, Mylan states that, during the Subject Time Period, Mylan used the Lotus Notes e-mail program.

# **INTERROGATORY NO. 30**

Identify the person who, or entity which, has performed an accounting review and/or audit of the financial statements of any of Your businesses for any financial reporting period during the Relevant Time Period.

#### **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as overbroad and unduly burdensome in that it is not limited to the State of California, the California Medicaid program, the Subject Drugs, the Subject Time Period, and the scope of the First Amended Complaint.

Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains words that are themselves vague, ambiguous, or undefined, including but not

limited to "accounting review" and "financial reporting period." Mylan further objects to this Interrogatory to the extent it seeks information protected by the attorney-client privilege, the work-product doctrine, or any other applicable privilege, rule, or doctrine.

Subject to and without waiving the foregoing general and specific objections, Mylan states that Deloitte & Touche LLP was its outside accounting firm during the Subject Time Period.

#### **INTERROGATORY NO. 31**

State the basis for any factual allegation that You made in Your Answer to the First Amended Complaint in Intervention.

## MYLAN'S OBJECTIONS AND RESPONSE

Mylan objects to this Interrogatory as overbroad and unduly burdensome to the extent it seeks "the basis for any factual allegation." Mylan further objects to this Interrogatory to the extent it seeks information protected by the attorney-client privilege, the work product doctrine, or any other applicable doctrine or privilege. Mylan further objects to this Interrogatory on the grounds that it is premature. Discovery has not yet concluded in this action and Mylan has not yet completed its investigation, analysis, or discovery of the facts relating to this case.

Subject to and without waiving the foregoing general and specific objections, Mylan refers California to its responses to Interrogatory Nos. 3, 12, 15, 21, 22, and 23.

# **INTERROGATORY NO. 32**

State the basis for any factual assertions that you, or anyone else on Your behalf, made in support of Your Motion or Motions to Dismiss filed in this action.

Mylan objects to this Interrogatory as overbroad and unduly burdensome to the extent it seeks "the basis for any factual allegation." Mylan further objects to this Interrogatory to the extent it seeks information protected by the attorney-client privilege, the work product doctrine, the joint defense privilege, or any other applicable doctrine or privilege.

Subject to and without waiving the foregoing general and specific objections, Mylan refers California to its responses to Interrogatory Nos. 3, 12, 15, 21, 22, and 23.

#### **INTERROGATORY NO. 33**

Identify each person who had responsibility for communicating with and/or who actually communicated with representatives of each of the following entities with regard to entering into contracts to purchase any of the Identified Drugs during the Relevant Time Period: (a) CVS; (b) Rite Aid; (c) Target; (d) Walgreens, and (e) Wal-Mart.

#### **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the State of California, the California Medicaid program, the Subject Drugs and the scope of the First Amended Complaint.

Subject to and without waiving the foregoing general and specific objections, Mylan states that the following current and former Mylan employees from Mylan's Pricing and Contracts department have knowledge of Mylan's contracts with the above-named entities, if any: David Workman, Holly Roskovich, Craig Semon, Kylee Fink, Jill Dean, Katie Bennett, Nicole Matlick, Tracy Adams, E. Allen Lowther,

Courtney Wilson, Michael Dougan, Joe Duda, Howard Martin, Kevan Nipper, Mike Hatch, Krista Marko, Vincent Lucente, Andrea Spadafore Morris, Lexannna Twyman, Christine McArdle, Connie Hatcher, Violet Tsomidis, Stephanie Morris, Robert Cunard, Allison Davis, Kelly Jones, and Krista McKinnon. Mylan further states that these individuals should be contacted through Mylan's counsel, Kelley Drye & Warren LLP, 101 Park Avenue, New York, New York.

#### **INTERROGATORY NO. 34**

State Your net and gross profit or margin on each of the Identified Drugs during the Relevant Time Period.

# **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan objects to this Interrogatory as overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of relevant, admissible evidence to the extent that it is not limited to the State of California, the California Medicaid program, the Subject Time Period, and the scope of the First Amended Complaint. Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains words that are themselves vague, ambiguous, undefined, and interpreted differently by the parties, including but not limited to "net and gross profit," and "margin." Mylan further objects to this Interrogatory to the extent it requires Mylan to create data or process an unreasonably large amount of data, some of which Mylan cannot compute at all and some of which Mylan cannot compute without expending a significant amount of resources, and which is not reasonably calculated to lead to the discovery of admissible evidence.

#### **INTERROGATORY NO. 35**

Identify the person or persons most knowledgeable of the marketing program and marketing materials You used to support sales of each of the Identified Drugs during the Relevant Time Period.

#### **MYLAN'S OBJECTIONS AND RESPONSE**

Mylan further objects to this Interrogatory as vague and ambiguous because, *inter alia*, it contains words that are themselves vague, ambiguous, undefined, and interpreted differently by the parties, including but not limited to "marketing program," "marketing materials" and "used to support sales."

Subject to and without waiving the foregoing general and specific objections,

Mylan states that Jason Harper has knowledge regarding the marketing of the Subject

Drugs.

# **INTERROGATORY NO. 36**

Identify the person or persons most knowledgeable of Your calculation of net and gross profit or margin on each of the Identified Drugs during the Relevant Time Period.

#### MYLAN'S OBJECTIONS AND RESPONSE

Mylan refers to and incorporates herein its objections to Interrogatory No. 34.

Dated: November 15, 2007

KELLEY DRYE & WARREN LLP

By: /s Christopher C. Palermo
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Attorneys for Defendants Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc.

# **VERIFICATION**

I, Brian S. Roman, Associate General Counsel of Mylan Laboratories
Inc., have read the foregoing MYLAN LABORATORIES INC. AND MYLAN

# PHARMACEUTICALS INC.'S OBJECTIONS AND RESPONSES TO

**PAINTIFF'S FIRST SET OF INTERROGATORIES**. I am informed and believe that the matters stated therein are true, and on that ground allege that they are true.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on the 14th day of November, 2007.

COMMONWEALTH OF PENNSYLVANIA

Notarial Seal Janice S. Johnston, Notary Public Cecil Twp., Washington County My Commission Expires June 7, 2011

Member, Pennsylvania Association of Notaries

Brian Roman

Associate General Counsel Mylan Laboratories Inc. 1500 Corporate Drive

Suite 400

Canonsburg, Pennsylvania 15317

Dated: November 14, 2007

Sworn to and Subscribed Before me this

Fance S. Johnston

14<sup>4α</sup> day of November, 2007

# **CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on November 15, 2007, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s Christopher C. Palermo
/S Christopher C. I areano